510(k) Summary: KOH Express AF cardiac event recorder

Introduction

This document contains the 510(k) summary for the KOH Express AF cardiac event recorder (a modified King of Hearts Express +AF cardiac event recorder). In order to ensure labeling clarity and software traceability, we have assigned a new name and Part Number (PN) to the modified device, as follows:

Trade name of modified device: KOH Express AF cardiac event recorder
Internal Card Guard name CG-2500
Finished goods no.: FG-00094

The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	Card Guard Scientific Survival Ltd.,	
Establishment Registration Number	9681879	
Address	2 Pekeris St., P.O.B. 527, Rehovot, 76100, Israel	
Contact person:	Asher Kassel, Director of RA & QA, Card Guard Scientific Survival Ltd.	
Phone:	972-8-9484010 (direct)	Fax: 972-8-9484044
E-mail:	asherk@cardguard.com	
Date Prepared:	16 June 2011	
Primary predicate device	King of Hearts Express +AF cardiac event recorder cleared in K020825 on April 5, 2002	
Secondary predicate device	CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector cleared in K101639 on June 25, 2010	
Trade Name:	KOH Express AF cardiac event recorder	
Classification:	recorder, magnetic tape, medical	
Product Code:	DSH	
Regulation No:	870.2800	
Class:	II	

Device Description

The KOH Express AF cardiac event recorder ("KOH" or "KOH Express AF" in short) is designed for the diagnostic evaluation of transient cardiac symptoms. The KOH is capable of storing up to 10 minutes of ECG recordings in solid state non-volatile memory. The device uses a two-wire lead set for single channel ECG acquisition. Using looping memory, the device captures ECG data; both before and after the patient experiences a cardiac symptom through auto-recording, or manually after the patient presses the RECORD button. ECG events are transmitted later in the form of an FM-modulated acoustic tone, when the SEND button is depressed. The device is configured in a compact sized case.

Indications for Use:

This device is indicated for diagnostic evaluation of patients who experience transient symptoms such as:

- Dizziness
- Palpitations
- Syncope
- Chest pain

Contraindications for use:

Warning:

This device is contraindicated for use in combination with external cardiac defibrillators or high frequency surgical equipment. Disconnect the patient leads from the electrodes prior to performing external defibrillation or using electrosurgical equipment.

There are no known safety hazards connected with the use and operation of a cardiac pacemaker or any electrical cardiac stimulator and the KOH Express AF cardiac event recorder.

Summary of the Technological Characteristics / Principles of Operation

The principles of operation and inputs/outputs of the modified device (KOH Express AF cardiac event recorder) are the same or substantially equivalent to those of the predicate devices. The KOH Express AF cardiac event recorder device is comprised of an ECG sensor with a 2-wire ECG cable and electrodes. The sensor is carried by the patient and is snapped into two electrodes by using the ECG cable.

The KOH Express AF cardiac event recorder device records the ECG data and analyzes it for arrhythmias. The following arrhythmias are automatically detected by the KOH Express AF cardiac event recorder:

1. Tachycardia
2. Bradycardia
3. Atrial Fibrillation

The KOH Express AF device also supports manual recording of ECG data by the patient by means of pressing the "RECORD" button. The KOH Express AF stores the ECG data in a cyclic non-volatile ("Flash") memory. When an event is automatically or manually triggered, the ECG data since the pre-event time until the post-event time is copied into the event buffer. The event buffer can hold up 16 events with total time of up to 10 minutes of ECG data.

When the user is near a telephone, the sensor can transmit to the Monitoring Center the ECG data of the events that are stored using an FM modulation acoustic protocol.

Non-clinical performance data for the KOH Express AF device:

The modified KOH Express AF device has been subjected to extensive verification / validation testing. Final testing of the system included various performance tests and software validation tests designed to ensure that the device meets all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device:

- Software Verification and Validation
  - Software Functional Unit Verification
  - System Level Software Validation
  - Arrhythmia Detection Algorithm Performance Validation
- Hardware Verification and Validation

Voluntary Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005". The design of the KOH Express AF device conforms to the following voluntary standards:

1. ANSI/AAMI/ISO EC57:1998 (R) 2008: Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
2. ANSI/AAMI EC38:2007 Ambulatory Electrocardiograph
3. ISO 14971:2007: Medical devices – application of risk management to medical devices;
4. IEC 60601-1:1988, 2nd edition, Part 1, plus A1:1991 and A2:1995: Medical electrical equipment; Part 1: General requirements for safety
5. IEC 60601-1-4:2000, plus Amendment 1:2004: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems
6. IEC 62304:2006: Medical device software – Software life cycle processes
7. ISO 15223:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
8. ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
9. IEC 60601-1-2:2007, Medical electrical equipment; Part 1: 2. Collateral Std.: EMC; requirements and tests

Substantial Equivalence:

The KOH Express AF cardiac event recorder is substantially equivalent with respect to indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Card Guard Scientific Survival, Ltd.
c/o Mr. Clay Anselmo
President and CEO
Reglera, LLC
11925 W 1-70 Frontage Road North
Wheat Ridge, CO 80033 USA

AUG - 1 2011

Re: K111745
Trade/Device Name: King of Hearts Express AF Cardiac Event Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: July 25, 2011
Received: July 26, 2011

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111745 pg 1 of 1

Indications for Use

510(k) Number (if known): _____

Device Name: KOH Express AF cardiac event recorder

Indications for Use:

This device is indicated for diagnostic evaluation of patients who experience transient symptoms such as:

- Dizziness
- Palpitations
- Syncope
- Chest pain

Contraindications for Use:

Warning:

This device is contraindicated for use in combination with external cardiac defibrillators or high frequency surgical equipment. Disconnect the patient leads from the electrodes prior to performing external defibrillation or using electrosurgical equipment.

There are no known safety hazards connected with the use and operation of a cardiac pacemaker or any electrical cardiac stimulator and the King of Hearts Express AF cardiac event recorder.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111745